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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,976	01/30/2004	Keith V. Wood	341.020US1	6271

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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402-0938

EXAMINER

KOSSON, ROSANNE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/768,976

Applicant(s)

WOOD ET AL.

Examiner

Rosanne Kosson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 1, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-109 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-109 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 2-10, 11, 12, 15 and 107-109, drawn to a compound of Formula I comprising one functional group, wherein the functional group is one type of molecule listed in claim 10, and a method of making the compound, classified in class 532, subclass 517.
- II. Claims 2-9, 11-13, 15 and 107-109, drawn to a compound of Formula I comprising one functional group, wherein the functional group is one molecule depicted in claim 13, and a method of making the compound, classified in class 532, subclass 517.
- III. Claims 2-9, 11, 12, 14, 15 and 107-109, drawn to a compound of Formula I comprising two functional groups, and a method of making the compound, classified in class 532, subclass 517.
- IV. Claims 16-18, 21, 22, 25-27, 87-90, 97-99, 102, 103 and 106, drawn to a mutant dehalogenase or hydrolase that comprises an amino acid substitution at a position that functions in the activation of a water molecule, and a cell comprising this mutant enzyme, classified in class 435, subclass 195.
- V. Claims 16, 19, 20, 23, 24, 25-27, 87-90, 97, 100, 101, 104 and 105, drawn to a mutant dehalogenase or hydrolase that comprises an amino acid

substitution at a position that function in the formation of an ester intermediate, classified in class 435, subclass 196.

- VI. Claims 28-34, drawn to a mutant serine beta-lactamase comprising at least two amino acid substitutions, classified in class 435, subclass 231.
- VII. Claims 35-37 and 52-66, drawn to a method of detecting the presence or amount of a mutant hydrolase, in which the hydrolase has an amino acid substitution at a position that functions in the activation of a water molecule, classified in class 435, subclass 195.
- VIII. Claims 35, 38, 39 and 52-66, drawn to a method of detecting the presence or amount of a mutant hydrolase, in which the hydrolase has an amino acid substitution at a position that functions in the formation of an ester intermediate, classified in class 435, subclass 196.
- IX. Claims 40-42, 45, 46 and 52-66, drawn to a method of isolating a molecule, cell or organelle, comprising contacting a sample with a fusion protein comprising a mutant hydrolase, in which the hydrolase has an amino acid substitution at a position that functions in the activation of a water molecule, classified in class 435, subclass 195.
- X. Claims 40, 43, 44-46 and 52-66, drawn to a method of isolating a molecule, cell or organelle, comprising contacting a sample with a fusion protein comprising a mutant hydrolase, in which the hydrolase has an amino acid substitution at a position that functions in the formation of an ester intermediate, classified in class 435, subclass 196.

- XI. Claims 47-49, 52-66, 67, 68, 71-77 and 91-96, drawn to a method of labeling a cell, comprising contacting a cell comprising a mutant hydrolase with a substrate, in which the mutant hydrolase has an amino acid substitution at a position that functions in the activation of a water molecule, classified in class 435, subclass 195.
- XII. Claims 47, 50, 51, 52-77 and 91-96, drawn to a method of labeling a cell, comprising contacting a cell comprising a mutant hydrolase with a substrate, in which the mutant hydrolase has an amino acid substitution at a position that functions in the formation of an ester intermediate, classified in class 435, subclass 196.
- XIII - XXXVIII. Claims 78 and 107-109, drawn to a compound depicted in one of Formulas II - XXVII, and a method of making the compound, classified in class 532, subclass 503. The compound of Formula II is group XIII; the compound of Formula III is group XIV, etc.
- XXXIX. Claims 79-82 and 86, drawn to an isolated polynucleotide comprising a dehalogenase that is optimized for expression in a host cell, i.e., SEQ ID NO: 50, classified in class 536, subclass 23.2.
- XL. Claims 83 and 84, drawn to an isolated polynucleotide comprising a mutant dehalogenase that is optimized for expression in a host cell and that has at least 85% sequence identity to a wild-type dehalogenase, i.e., SEQ ID NO: 51, classified in class 536, subclass 23.2.

XLI. Claim 85, drawn to an isolated polynucleotide comprising a dehalogenase that is optimized for expression in a host cell and that has less than 90% sequence identity to SEQ ID NO: 51, classified in class 536, subclass 23.2.

The inventions are distinct, each from the other because of the following reasons.

The inventions of Groups I-VI and XIII-XLI are unrelated because each of these inventions is drawn to a different product. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each of these different products has its own structure, chemical properties and functions. The products of Groups I-III are various biological and organic chemical derivatives of Formula I. The products of Groups IV-VI are various mutant enzymes. The products of Groups XIII-XXXVIII are organic molecules that vary widely in structure. The products of Groups XXXIX-XLI are various DNA molecules. Therefore, these inventions are patentably distinct.

The inventions of Groups VII-XII are unrelated because each of these inventions is drawn to a different method, each method comprising different steps. Groups VII and VIII are drawn to methods of detecting the presence or amount of a mutant hydrolase, the mutant hydrolase being a different enzyme in each method. Groups IX and X are drawn to methods of isolating a molecule, cell or organelle, each method using a different enzyme. Groups XI and XII are drawn to methods of labeling a cell, each

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method using a cell comprising a different enzyme. Therefore, these inventions are patentably distinct.

The inventions of Groups VII and VIII each recite the step of contacting a mutant hydrolase with a substrate comprising any one or more functional groups. Thus, the compounds of Groups I-VI and XIII-XLI are not required for these methods. Therefore, the inventions of Group VII and Groups I-VI and XIII-XLI, and the inventions of Group VIII and Groups I-VI and XIII-XLI are patentably distinct.

The inventions of Groups IX and X each recite the step of contacting any molecule, cell or organelle with a fusion protein comprising a mutant hydrolase and a substrate comprising any one or more functional groups. Thus, the compounds of Groups I-VI and XIII-XLI are not required for these methods. Therefore, the inventions of Groups IX and Groups I-VI and XIII-XLI, and the inventions of Group X and Groups I-VI and XIII-XLI are patentably distinct.

The inventions of Groups XI and XII each recite the step of labeling a cell by contacting a cell comprising a mutant hydrolase with a substrate comprising any one or more functional groups. Thus, the compounds of Groups I-VI and XIII-XLI are not required for these methods. Therefore, the inventions of Group XI and Groups I-VI and XIII-XLI, and the inventions of Group XII and Groups I-VI and XIII-XLI are patentably distinct.

Claim 1 link(s) inventions I-III. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1.

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Claim 16 link(s) inventions IV and V. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 16.

Claim 35 link(s) inventions VII and VIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 35.

Claim 40 link(s) inventions IX and X. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 40.

Claim 47 link(s) inventions XI and XII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 47.

Upon the allowance of a linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The search for any one group is not required for any other group, thereby creating an undue burden of search and examination. Burden lies not only in the search of U.S. patents, but in the search for literature and foreign patents and in the

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examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement. Further, the different groups have acquired a separate status in the art, as shown in part by their different classifications. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is clearly proper.

This application also contains claims directed to the following patentably distinct species of the claimed invention:

- a) each one of the functional groups listed in claim 10;
- b) each one of the compounds depicted in claim 13;
- c) each one of the functional properties listed in claim 15;
- d) each one of the proteins of interest listed in claim 26;
- e) each one of the proteins of interest listed in claim 34;
- f) each one of the functional groups listed in claim 59;
- g) each one of the functional properties listed in claim 63;
- h) each one of the proteins of interest listed in claim 66;

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species in group a) – h) corresponding to the elected group I – XLI for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 25, 33, 35, 40 and 47 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

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readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

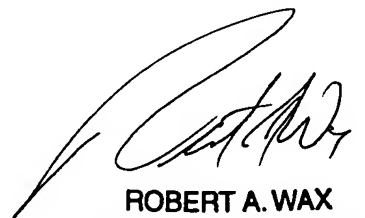
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
Art Unit 1651

rk
2005-05-19



ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653